

[2007] [OP0158] LONG TERM EFFICACY OF STRONTIUM RANELATE IN REDUCING THE RISK OF VERTEBRAL AND NON-VERTEBRAL INCLUDING HIP FRACTURES IN POST MENOPAUSAL OSTEOPOROTIC WOMEN OVER 5 YEARS

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Objectives: The objective of this work was to describe the 5-year long term antifracture efficacy of strontium ranelate in TROPOS1 study.

Methods: Strontium ranelate is a recent anti-osteoporotic treatment which efficacy is based on a new and unique mode of action both increasing bone formation and decreasing bone resorption.

The TROPOS (TReatment Of Peripheral OSteoporosis) phase III study, performed in 75 European and Australian centres, enrolled 5091 Caucasian women with postmenopausal osteoporosis with mean age (SD) of 76.7(5) years and with mean femoral neck BMD T-score (SD) of -3.1(0.6). The patients were randomly assigned to receive strontium ranelate 2g/day or placebo for 5 years as well as a supplementation with calcium and vitamin D according to their baseline status. The main statistical analysis was performed over 3 years of treatment and demonstrated efficacy of strontium ranelate at vertebral and non-vertebral sites including a significant decrease in hip fracture risk demonstrated in patients at risk over the same treatment period.

Results: The 5-year results of TROPOS confirmed the long term vertebral and non-vertebral antifracture efficacy of strontium ranelate in the intent-to-treat population (n=2479 in strontium ranelate group and 2453 in placebo group) already shown over 3 years. The vertebral risk of fracture was significantly reduced by 24% (RR=0.76; 95% CI[0.65;0.87] Cox model: p<0.001). The non-vertebral fracture risk was decreased by 15% (RR=0.85; 95% CI[0.77;0.99] Cox model: p=0.03) In addition, the hip antifracture efficacy of strontium ranelate was assessed in women at particular high risk (age > 74 years with lumbar and femoral neck BMD T- score < -2.4 according to NHANES normative values). In these patients, (n= 1128, mean age (SD) 79.2(4.4), mean lumbar T-score= -4.2, mean femoral neck T-score= -3.0), strontium ranelate demonstrated a 43% reduction of the risk of hip fracture (RR=0.57; 95% CI[0.33;0.97] Cox model: p=0.036).

Conclusion: These results confirm a sustained efficacy of strontium ranelate over five years against vertebral, non-vertebral and hip fractures.

References: 1. Reginster JY et al (2005) J Clin Endo Metab. 90:2816-2822.

Abstract Session: Osteoporosis

Citation: Ann Rheum Dis 2007;66(Suppl II):102